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研究報告書

「高難度新規医療技術の導入プロセスに係る診療ガイドライン等の評価・向上に関する特別研究」分担研究報告書

国内外での高難度新規医療技術に関するガイドラインの現況を情報収集整理

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研究要旨
本研究は、高難度医療技術に関するガイドラインの向上に向けた提言を行うため、国内外の高難度医療技術に関する関連文書を収集・分析する等の調査により、高難度医療技術に関するガイドラインの国内外の実態把握を行った。具体的には、高難度新規医療技術に関する基本的な考え方の策定にあたって収集された国内の関連文書及び海外については米英の公的機関が保有する診療ガイドラインデータベースの網羅的な検索等により確認された関連文書の分析を行った。
国内ガイドライン等の調査により、高難度医療技術の関連文書には、「ガイドライン」のほか、「実施基準」、「提言」といった名称の文書もあり、また、学会員限定で公開されている文書もあった。海外ガイドラインの調査により、特定の医療技術（例えばロボット手術）に関する関連文書について、米国では学会レベルで提唱する指針、英国では国立保健医療研究所が策定するガイダンスが少数例確認された。また、本分担研究班が調査した限り、海外の状況として、高難度新規医療技術の導入するにあたって政府レベルで定める包括的な針は確認できなかった。
以上を踏まえると、我が国において高難度医療新規医療技術の導入に関する、政府レベルでの統一的なルールを定めたことは、大変有意義であり革新的な取組と言える。関連学会を中心にさらに充実した高難度新規医療技術に関連するガイドライン等の整備及び周知を図っていき、また、医療機関においてこれらの制度を適正に運用することにより、日本の医療の向上に寄与することが期待される。

A. 研究目的

厚生労働省は、大学附属病院等において、医療安全に関する重大な事案が相次いで発生していることをうけ、社会保障審議会医療分科会が平成 27 年4月にとりまとめた「特定機能病院等の医療安全管理体制に関する意見」（以下「意見書」という。）の内容も踏まえ、2016 年 6 月 10 日、医療法施行規則等を改正し、高難度医療新規医療技術を導入するにあたってのプロセスに統一的なルールを定めることになった。意見書においては、「高難度の新規医療技術（以下「高難度新規医療技術」という。）に関連して死亡事案が相次いで発生したことを踏まえ、関係学会に対し、高難度新規医療技術の導入を検討するに当たっての、インフォームド・コンセントの在り方、術者の技量や指

導体制などの、医療安全に関する基本的な考え方を検討・整理することを要請する」とされており、当該ルールを説明する医政局長通知においても「高難度新規医療技術の提供のプロセスに関する規程を策定するときは、関係学会から示される「高難度新規医療技術の導入に当たっての基本的な考え方」やガイドライン等を参考にすること」とされている。

本研究は、これらを背景に、国内外の高難度新規医療技術に関するガイドライン等の内容を調査することにより、実態把握をするとともに、今後の高難度医療技術に関するガイドラインの向上に向けた提言を行うことを目的とする。

B. 研究方法

1）国内ガイドラインの調査

「高難度新規医療技術の基本的考え方」の策定経緯の中で、國土研究班の班員の協力を得て集められた国内の高難度新規医療技術の導入プロセスに関連すると考えられる国内の指針・ガイドライン 25 件、日本医学会を通じて、基本 18 領域の関係学会に導入プロセスに関連すると考えられる指針・ガイドライン等の提供を求めて集まった 13 件の関連文書（以下「関連文書」という。）のうち、Web 上で公開されている 32 件について、高難度新規医療技術の導入にあたって必要とされている「術者の要件」、「指導体制」、「その他医療安全に関する事項」、「インフォームド・コンセントに関する事項」の記載（（以下「関連記載」という。）の有無等について文献調査を行った。

2）海外ガイドラインの調査

手術・手技に関する国外の診療ガイドライン等について文献調査を行い、その記載項目や策定方法、エビデンスの収集方法等について調査した。具体的には、英米における公的機関（米国 医療研究品質庁 (Agency for Healthcare Research and Quality（以下「AHRQ」という。））、英国 国立保健医療研究所（National Institute for Health and Care Excellence（以下「NICE」という。））や学術団体等が掲載している手術・手技等のガイドラインの有無及び、その記載項目等を確認した。また、シンガポール大学で実施臨床を行った河野の経験から、シンガポール国立大学における高難度新規医療技術の導入に関する現状を報告し、また、シンガポール国立大学外科教授 2 名より、本件に関する聞き取り面談調査を行った。

(倫理面への配慮)

倫理面でとくに配慮するべき問題点はない。

C. 研究結果

1）国内ガイドラインの調査結果

32 件の関連文書の中で、高難度医療技術の導入プロセスに関する記載項目、①「術者の要件」、②「指導体制」、③「その他医療安全に関する事項」のいずれかを含んでいるガイドラインは 22 件あった。 このうち「術者の要件」は 22 件、指導体制は、11 件、「その他医療安全に関する事項」は 13 件に含まれていた。これらの関連記載は、ガイドラインの総論の一部や Q&A の一つとして記載される場合もあった。これらの関連文書の名称は、「ガイドライン」9 件、「基準」7 件、「指針」4 件、「その他」2 件、だった（資料 15 添参照）。

2）海外ガイドラインの調査結果

（1）米国ガイドラインの調査状況

米国 AHRQ が運営し、各国の診療ガイドラインを収載する National Guideline Clearinghouse(NGC)のウェブサイトにおいて、「Surgery」という カテゴリーを調査したところ、390 件（2004～2016 年発行）のガイドラインが確認でき、そのうち、NGC の掲載基準※に合致するガイドラインは 76 件

(2011 ～2016 年発行)であった(資料16)。これら76件の文献のうち、タイトルから2件が該当文献として候補に挙げられたが、本文内容を確認した結果、高難度新規医療技術に関連する文献は見当たらなかった。

上記のデータベース検索では、米国における高難度医療技術に関連するガイドラインを確認できなかったが、分担研究者(河野)がシンガポール在住時に使用していた高難度新規医療技術に関する指針・ガイドラインとして、「A Consensus document on Robotic Surgery」には、術者の要件や病院としての医療安全体制等の高難度医療技術に関連する記載が含まれていた(資料16参照)。

(2)英国ガイドライン調査状況

① 英国が運営し、診療ガイドラインをはじめとするガイダンス全般を収載する NICE のウェブサイト上において、手術や検査等の手技に関するガイダンスを掲 載 す る「Technology appraisal guidance」 お よび「Medical technologies guidance」のカテゴリー内を調査したところ、それぞれ 188 件、 28 件(ともに 2011～2016 年発行)のガイダンスが確認できた。これらの文献のタイトルから高難度新規医療技術に関連する文献は見当たらなかった。

② 上記の NICE のウェブサイト上全般において、以下に示す Key Words にて 再度調査を行ったところ、8 件の文献が確認できた。これら 8 件の本文内容か、「Laparoscopic repair of abdominal aortic Aneurysm 」、「 Laparoscopic retroperitoneal lymph nodedissection for testicular cancer」の 2 件が該当文献として確認できた。 内容は薄いものの(1 ページのみ)、「技術的に難であることを Inform すること」「データベースに登録すること」「集学的チームで行うこと」のガイダンスが 示されていた(資料 17 参照)。

(Key Words)

□ Surgeon credentialing □ Training guidelines □ Privileging qualified surgeons □ Minimal requirements for granting privileging surgeons □ Technically demanding surgery

(3)その他

英米以外の海外の状況も把握するため、シンガポール国立大学外科教授 2 名より、本件に関する聞き取り面談調査を行った結果、シンガポールにおいては、国が定めた統一的なルールはないが、病院独自の取り決めとして、高難度新規医療技術の提供にあたって、事前審査を行っていることがわかった(資料 18 参照)。

D. 考察

国内ガイドライン等の調査結果により、高難度医療技術の関連文書には、「ガイドライン」のほか、「実施基準」、「提言」といった名称の文書もあり、また、学会員限定で公開されている文書もあった。高難度新規医療技術の導入にあたって、特定機能病院等は、ガイドラインという名称のみならず、実施基準、提言といった、関係学会が発出する高難度新規医療技術の関連文書に基づき評価することが求められる。また、関係学会は、策定した関連文書について、病院又は学会員からのアクセシビィリティの向上を図るとともに、各関連文書の中で、導入にあたっての評価項目となっている関連記載についてわかりやすく情報発信することが望ましい。

今回、米国・英国の診療ガイドラインデータベース検索により、カテゴリー検索及び Key

Word 検索をしたところ、高難度新規医療技術に関する指針・ガイドラインは 2 件しか該当しなかった。他方、米国学会のワーキンググループが作成している「A Consensus document on Robotic Surgery」は高難度新規医療技術の関連文書に該当することから、海外においても、個別学会の出している高難度新規医療技術の関連文書が、公的機関が運営する診療ガイドラインのデータベース検索では確認できず、個別学会のホームページ等に掲載されている可能性は高い。確認された海外ガイドライン等の少数例では、「術者の要件」、「指導体制」、「そのほか医療安全に関する事項」、「病院による事前審査」等の記載が認められており、海外においても、特定の医療行為においては、学会や病院を中心として、高難度医療技術の提供にあたっては、一定の監査システムや条件の中で行われているものと考えられた。

また、シンガポール大学の外科教授からの聞き取り調査により、海外において、政府レベルで高難度新規医療技術に関する導入プロセスについて、統一的なルールを課している事実は確認できなかった。

今回、国内外の高難度医療技術に関するガイドラインを整理することにより、今後も医療技術の進展に伴い新たに学会で作られる高難度医療技術ガイドラインの質の向上に資する知見を得ることができた。

E. 結論

本分担研究班の調査結果により、国内外の高難度新規医療技術に関するガイドライン等の実態が把握できた。国内の高難度医療技術の関連文書には、「ガイドライン」のほか、「実施基準」、「提言」といった名称の文書もあり、また、学会員限定で公開されている文書もあった。海外ガイドラインの調査により、特定の医療技術（例えばロボット手術）に関する関連文書について、米国では学会レベルで提唱する指針、英国では国立保健医療研究所が策定するガイダンスが少数例確認された。また、本分担研究班が調査した限り、海外の現状として、高難度新規医療技術の導入するにあたって政府レベルで定める包括的な指針は確認できなかった。

以上を踏まえると、我が国において高難度医療新規医療技術の導入に関する、政府レベルでの統一的なルールを定めたことは、大変有意義であり革新的な取組と言える。関連学会を中心にさらに充実した高難度新規医療技術に関連するガイドライン等の整備及び周知を図っていき、また、医療機関においてこれらの制度を適正に運用することにより、日本の医療の向上に寄与することが期待される。

F. 研究発表

講演発表：なし
論文発表：なし
学会発表：なし

知的財産権の出願・登録状況（予定を含む。）

1. 特許取得：なし
2. 実用新案登録：なし
3.その他：特になし

資料15

高難度医療技術に関連する国内ガイドライン等についての調査結果

注）下記の文書は、「高難度医療技術に関する基本的な考え方」を策定する経緯で収集された関連文書であり、本ガイドラインの対象医療技術だからといって、高難度医療技術に該当するわけではない。

No	ガイドライン名	学会	術者の要件	指導体制	その他医療安全に関する事項	ICに関する事項
1	内視鏡下外科手術施行にあたってのガイドライン	日本内視鏡外科学会	○	○	－	－
2	内視鏡手術支援ロボット手術導入に関する提言	日本内視鏡外科学会	○	○	○	－
3	新医療機器に関する見解(2012.12.06更新)	日本内視鏡外科学会	―	－	－	－
4	日本内視鏡外科学会（JSES）の内視鏡手術支援ロボット導入条件の遵守喚起	日本内視鏡外科学会	―	－	－	－
5	経皮的経管的脳血栓回収機器 適正使用指針第2版・実施基準	日本脳卒中学会、日本脳神経外科学会、日本脳神経血管内治療学会	○	－	○	－
6	頭蓋内動脈ステント（動脈硬化症用） 適正使用指針（2013年12月版）	日本脳卒中学会、日本脳神経外科学会、日本脳神経血管内治療学会	○	－	○	－
7	頭蓋内動脈ステント（脳動脈瘤治療用Flow Diverter）適正使用指針第2版（2015年4月版）・実施基準	日本脳卒中学会、日本脳神経外科学会、日本脳神経血管内治療学会	○	－	○	－
8	脳神経領域医療機器「エンボスフィア」及び「ヘパスフィア」の適正使用に係る体制等の要件	日本脳神経血管内治療学会、日本脳神経外科学会、日本インターベンショナルラジオロジー（IVR）学会	○	○	－	－
9	経カテーテル的大動脈弁置換術実施施設基準	経カテーテル的大動脈弁置換術関連学会協議会	○	○	○	－
10	ヒト（自己）骨格筋由来細胞シート使用の施設基準および実施医基準	ヒト（自己）骨格筋由来細胞シート関連学会協議会	○	－	○	－
11	植込型補助人工心臓認定施設・医師更新基準	補助人工心臓治療関連学会協議会	○	○	○	―
12	心臓移植実施施設認定基準	心臓移植関連学会協議会	○	○	○	○
13	胸部大動脈瘤ステントグラフト実施基準	日本ステントグラフト実施基準管理委員会	○	○	○	―
14	4学会会員への注意喚起（平成26年11月17日）	日本内視鏡外科学会、日本肝胆膵外科学会、日本消化器外科学会、日本外科学会	―	－	－	○
15	てんかんに対する迷走神経刺激療法の実施ガイドライン	日本てんかん学会	○	○	－	－
16	てんかん外科の適応に関する指針	日本てんかん学会	―	－	－	－
17	内側側頭葉てんかんの診断と手術適応に関するガイドライン	日本てんかん学会	―	－	－	－
18	新皮質てんかんの外科治療ガイドライン	日本てんかん学会	―	－	－	－
19	脳腫瘍診療ガイドライン前文2015版	日本脳腫瘍学会	―	－	－	－
20	脳腫瘍診療ガイドライン：中枢神経系原発悪性リンパ腫	日本脳腫瘍学会	―	－	－	－
21	泌尿器腹腔鏡手術ガイドライン2014年版	日本泌尿器内視鏡学会		－	－	－
22	泌尿器科領域における da Vinci 支援手術を行うに当たってのガイドライン	日本泌尿器科学会 日本泌尿器内視鏡学会	○	○	○	○
23	婦人科悪性腫瘍に対するロボット支援下手術に関する指針	日本産科婦人科学会	○	○	○	○
24	加齢黄斑変性症に対する光線力学的療法のガイドライン	日本眼科学会	○	-	-	○
25	白内障手術併用眼内ドレーン使用要件等基準	日本眼科学会	○	-	-	―
26	屈折矯正手術のガイドライン	日本眼科学会	○	-	-	○
27	水晶体 拡張リング使用ガイドライン	日本眼科学会	○	-	-	○
28	産婦人科内視鏡手術ガイドライン	日本産婦人科学会	○	○	-	○
29	覚醒下脳手術施設認定制度 指針	日本脳神経外科学会	○	－	○	－
30	体外循環による新生児急性血液浄化療法ガイドライン	日本小児科学会	-	-	-	○
31	先天性および小児期発症心疾患に対するカテーテル治療の適応ガイドライン	日本小児科学会	○	-	-	－
32	先天性心疾患、心臓大血管の構造的疾患（structural heart disease）に対するカテーテル治療のガイドライン	日本小児科学会	○	-	○	○

※「術者の要件」、「指導体制」、「その他医療安全に関する考え方」については、厚生労働省特別研究班（國土班）「高難度新規医療技術の導入に当たっての基本的な考え方」の記載に相当するものの有無で判断している。

※上記のガイドラインは、2017年３月現在にてWeb上にて公開されていたガイドライン

National Guideline Clearinghouseにおける外科関連の診療ガイドライン
（掲載基準に合致するもののみ）

No	Publish Year	Title of CPG
1	2016.3	Practice guidelines for the prevention, detection, and management of respiratory depression associated with neuraxial opioid administration: an updated report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine.
2	2016.3	Guideline for prevention of retained surgical items.
3	2016.1	Guideline for care of the patient receiving moderate sedation/analgesia.
4	2015.11	Blood transfusion.
5	2015.11	Guideline for prevention of unplanned patient hypothermia.
6	2015.9	Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures.
7	2015.8	Treatment of Cushing's syndrome: an Endocrine Society clinical practice guideline.
8	2015.7	Everolimus for preventing organ rejection in liver transplantation.
9	2015.7	Merkel cell carcinoma.
10	2015.6	Lower urinary tract symptoms in men: assessment and management.
11	2015.6	Venous thromboembolism in adults admitted to hospital: reducing the risk.
12	2015.3	Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication.
13	2015.2	Bladder cancer: diagnosis and management.
14	2015.2	Platelet transfusion: a clinical practice guideline from the AABB.
15	2015.2	Practice guidelines for perioperative blood management: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Blood Management.
16	2015.1	Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people.
17	2015.4	Peyronie's disease: AUA guideline.
18	2014	Guideline for autologous tissue management.
19	2015	ACR Appropriateness Criteria® radiologic management of hepatic malignancy.
20	2015.1	American Geriatrics Society abstracted clinical practice guideline for postoperative delirium in older adults.
21	2015	ACR Appropriateness Criteria® routine chest radiography.
22	2014.12	Intrapartum care: care of healthy women and their babies during childbirth.
23	2014.11	Acromegaly: an Endocrine Society clinical practice guideline.
24	2014.11	
25	2014	Guideline for preoperative patient skin antisepsis.
26	2014.9	Optimal systemic therapy for early female breast cancer.
27	2014.9	Locoregional therapy of locally advanced breast cancer (LABC).
28	2014.9	Dyspepsia and gastro-oesophageal reflux disease. Investigation and management of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease, or both.
29	2014.9	Drug allergy: diagnosis and management of drug allergy in adults, children and young people.
30	2014.8	Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum.
31	2014.7	Systemic therapy for patients with advanced human epidermal growth factor receptor 2-positive breast cancer: American Society of Clinical Oncology clinical practice guideline.
32	2014.7	2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society.
33	2014.6	Pheochromocytoma and paraganglioma: an Endocrine Society clinical practice guideline.
34	2014.6	Guidelines for laparoscopic peritoneal dialysis access surgery.
35	2014.6	Management of primary cutaneous squamous cell carcinoma. A national clinical guideline.
36	2014.6	Timing and type of surgical treatment of Clostridium difficile-associated disease: a practice management guideline from the Eastern Association for the Surgery of Trauma.
37	2014.5	Sentinel lymph node biopsy for patients with early-stage breast cancer: American Society of Clinical Oncology clinical practice guideline update.
38	2014.4	Clinical practice guideline on diagnosis and treatment of hyponatraemia.
39	2014.4	Pressure ulcers: prevention and management of pressure ulcers.
40	2014.3	Medical management of kidney stones: AUA guideline.

National Guideline Clearinghouseにおける外科関連の診療ガイドライン
（掲載基準に合致するもののみ）

41	2014.2	Cervical spine injury medical treatment guidelines.
42	2014.2	Low back pain medical treatment guidelines.
43	2014.2	Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44).
44	2014	Guideline for care of the patient receiving local anesthesia.
45	2014	Interventions for prevention and treatment of pressure ulcers. In: Prevention and treatment of pressure ulcers: clinical practice guideline.
46	2014	Adult weight management evidence-based nutrition practice guideline
47	2014	VA/DoD clinical practice guideline for the management of upper extremity amputation rehabilitation.
48	2014	ACR Appropriateness Criteria® aggressive nonmelanomatous skin cancer of the head and neck.
49	2014	ACR Appropriateness Criteria® blunt chest trauma – suspected aortic injury.
50	2014	Treatment of pressure ulcers. In: Prevention and treatment of pressure ulcers: clinical practice guideline.
51	2014	Blood transfusion in the management of sickle cell disease. In: Evidence-based management of sickle cell disease.
52	2014	ACR Appropriateness Criteria® radiologic management of lower gastrointestinal tract bleeding
53	2014	Special populations. In: Prevention and treatment of pressure ulcers: clinical practice guideline.
54	2014	ACR Appropriateness Criteria® resectable stomach cancer.
55	2014	Guideline for surgical attire.
56	2014	Managing acute complications of sickle cell disease. In: Evidence-based management of sickle cell disease.
57	2014	ACR Appropriateness Criteria® radiologic management of infected fluid collections.
58	2014	ACR Appropriateness Criteria® ductal carcinoma in situ.
59	2014	Guideline for management of wounds in patients with lower-extremity arterial disease.
60	2014	VA/DoD clinical practice guideline for screening and management of overweight and obesity
61	2013	Management of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians.
62	2013.8	Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer.
63	2013.5	Summary of evidence-based guideline: periprocedural management of antithrombotic medications in patients with ischemic cerebrovascular disease. Report of the Guideline Development Subcommittee of the American Academy of Neurology.
64	2013	Clinical practice guideline on the management of invasive meningococcal disease.
65	2013.1	Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia.
66	2013	Clinical practice guidelines for the management of rotator cuff syndrome in the workplace.
67	2012.11	Depth of anaesthesia monitors - Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M.
68	2012.8	SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast-enhanced ultrasound imaging of the liver.
69	2012.7	Red blood cell transfusion: a clinical practice guideline from the AABB.
70	2012.5	Early thrombus removal strategies for acute deep venous thrombosis: clinical practice guidelines for the Society for Vascular Surgery and the American Venous Forum.
71	2012	Patient blood management guidelines: module 4 - critical care.
72	2012	Patient blood management guidelines: module 2 - perioperative.
73	2011.9	Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease.
74	2011.5	The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum.
75	2011	Patient blood management guidelines: module 1 - critical bleeding/massive transfusion.
76	2011	Guideline for processing flexible endoscopes.

国外の高難度医療技術に関連するガイドラインの事例

-添付資料①-

A Consensus Document on Robotic Surgery

Prepared by the SAGES-MIRA Robotic Surgery Consensus Group

（Surg Endosc. 2008 Feb;22(2):313-25、http://.sages.org）

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
The Minimally Invasive Robotic Association (MIRA)

本コンセンサスは24ページにわたり、ロボット手術の適応、リスク、コストベネフィット、術者の資格認定とトレーニングにつき、述べられている。

資格認定について（和訳して要点を抜粋）

1. 術者の資格認定は、個々の医療施設あるいは病院での特別委員会で審議される。各Unit長は、ロボット手術を開始するにあたり、この特別委員会に術者の資格認定を申請する。この特別委員会は、病院および適切な政府機関の認定が必要である。

2. 術者は、外科レジデントプログラム終了、該当疾患分野の専門医の取得が必要

3. 術者は　該当疾患分野で十分な手術経験があり、良好な成績である必要がある（Unit長の承認が必要）

4. 初回ケースでは、その技術のExpertのReviewあるいはAssistが必要である（Expertの認定は、Unit長および特別委員会の認定）。

5. 該当手術は、専任化した診療チームを形成する必要がある

6. ロボット手術開始後は、適応な期間、適当な症例数までは、手術の内容と結果についてMonitorが必要である。期間と症例数は特別委員会が決定。

7. 術者の資格認定は、一定期間で更新する必要があり、これには、該当技術の結果の評価と、関連学会への出席などの義務をふくみ、これらの結果によっては、資格認定を剥奪することも可能である（特別委員会の責任）

-添付資料②-

Laparoscopic repair of abdominal aortic aneurysm
Interventional procedure guidance
(Published: 22 August 2007　nice.org.uk/guidance/ipg229)

本ガイダンスは6ページにわたり、腹腔鏡下の腹部大動脈瘤修復術について、その適応、実施の要件、技術の概要、リスク、ベネフィットが述べられている。

実施の要件について（和訳して要点を抜粋）

1. 本術式は、特別の監査システム下あるいは臨床試験として実施すべきである。

2. 実施にあたり、The clinical governance leads in their Trustsに報告。

3. 本術式は、術式に関する特別のICが必要であり、他の手術術式の呈示、開腹術への移行の可能性などの説明が必要。

4. 本術式に関する情報をNational Vascular Databaseへの登録が必須。

5. 患者の適応は、本分野に精通した集学的チームで判断する必要がある。

6. 本術式は、血管外科に精通し、かつ、高度な腹腔鏡手術のトレーニングを受けた外科医が実施すること。

-添付資料③-

Laparoscopic retroperitoneal lymph node dissection for testicular cancer Interventional procedure guidance

(Published: 22 March 2006 nice.org.uk/guidance/ipg158)

本ガイダンスは5ページにわたり、精巣ガンに対する腹腔鏡下後腹膜リンパ節郭清術について、その適応、術者の要件、技術の概要、リスク、ベネフィットが述べられている。

実施の要件について（和訳して要点を抜粋）

1. 本術式は、特別の監査システム下あるいは臨床試験として実施すべきである。

2. 実施にあたり、The clinical governance leads in their Trustsに報告

3. 本術式は、術式に関する特別のICが必要であり、重篤な合併症の可能性などの説明が必要

4. 本術式の結果の監査、評価が必須

5. 術者は、該当分野の開腹術、および腹腔鏡下手術の十分な経験が必要であり、実施にあたっては集学的チーム構成が必要。

A Consensus Document on Robotic Surgery

Prepared by the SAGES-MIRA Robotic Surgery Consensus Group

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〔添付資料1　原文〕

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Introduction

Robotic surgical devices have developed beyond the investigational stage and are now routinely used in minimally invasive general surgery, pediatric surgery, gynecology, urology, cardiothoracic surgery and otorhinolaryngology. Robotic devices continue to evolve and – as they become less expensive and more widely disseminated – will likely become more frequently utilized in surgical procedures. The leadership of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) felt that guidelines for the usage of robots in surgery were lacking, and that the surgical community would benefit from a consensus statement on robotic surgery including guidelines for training and credentialing.

To accomplish this task, SAGES and MIRA assembled an international multidisciplinary consensus group to draft a consensus statement. The SAGES-MIRA Robotics Consensus Conference was convened at Mount Sinai Medical Center in New York City on June 2-3, 2006. The task force addressed four distinct questions it felt were central to the use of robots in surgery:

- **Training and credentialing**: How should training for robotic surgery be accomplished? What is the appropriate process for credentialing robotic surgery?
- **Clinical applications of robots in surgery**: What are the appropriate clinical applications for robotic surgery; has efficacy been demonstrated for these applications?
- **Risks of Surgery and Cost-Benefit Analysis**: What are the physical risks of robotic surgery to the patient? What financial costs are involved in robotic surgery and are these costs justified?
- **Research**: What are the important unanswered questions in robotic surgery? What direction should future research take?

After meeting and presenting data regarding these issues in a didactic forum, the Robotic Task Force faculty was divided into 4 working groups to address these issues separately. The faculty then reconvened to review the working groups' conclusions and arrive at a generalized consensus. The results of these proceedings are presented in this document.

Definitions

"Robotic surgery" is an imprecise term, but it has been widely used by both the medical and lay press and is now generally accepted. The term refers to surgical technology that places a computer-assisted electromechanical device in the path between the surgeon and the patient. A more scientifically accurate term for current devices would be "remote tele-presence

manipulators" since available technology does not generally function without the explicit and direct control of a human operator. For the purposes of the document, we define robotic surgery as a surgical procedure or technology that adds a computer technology enhanced device to the interaction between a surgeon and a patient during a surgical operation and assumes some degree of control heretofore completely reserved for the surgeon.

As an example, in laparoscopic surgery the surgeon directly controls and manipulates tissue, albeit at some distance from the patient and through a fulcrum point in the abdominal wall. This differs from current robotic devices, where the surgeon sits at a console – typically in the operating room but outside the sterile field – directing and controlling the movements of one or more robotic arms. While the surgeon still maintains control over the operation, the control is indirect and is effected from an increased distance.

This definition of robotic surgery encompasses micromanipulators as well as remotely-controlled endoscopes in addition to console-manipulator devices. The key elements are enhancements of the surgeon's abilities, be they vision, tissue manipulation, or tissue sensing, and alteration of the traditional direct local contact between surgeon and patient.

Clinical Environment

Surgical robots are considerably more complex, both electrically and mechanically, than traditional devices used in the operating room environment. In addition, they involve direct contact with the patient, both externally and internally. These important features differentiate surgical robots from other equipment such as operating microscopes, intraoperative imaging devices and traditional operating room instruments.

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In addition to the surgeon and surgical assistant, all personnel in the operating room must be appropriately trained to handle this equipment. There are currently no standard criteria set forth for registered nurses, operating room technicians, or surgeons with respect to appropriate training for managing these instruments in the operating room. However, at a minimum, operating room personnel should be trained according to the manufacturer's training guidelines, and should have the opportunity to be "doubled up" with an experienced nurse or operating room technician during their early experience.

It is highly recommended that teams using such instruments – surgeons, technicians, nurses, and possibly manufacturing representative – meet on a periodic basis to stay current in their training and to learn of updates or changes to the hardware or software. In this way, emerging problems may be quickly identified and addressed.

I. Surgeon Training and Credentialing

In order to maintain the highest levels of patient care today and in the future, we must ensure that surgeons are adequately trained in the use of surgical robots prior to clinical use. Training and credentialing are separate but intimately related issues. Credentialing can only be granted by the individual institutions where surgeons work. We have included formal guidelines for credentialing in Appendix I of this document and guidelines for robotic surgery training in

Appendix II.

There are two broad aspects to training with robotic systems. The first is technical training and capability. The surgeon must have both a knowledge base and a practical working familiarity with these complex devices before clinical use. In addition to all standard operating procedures, this training must include how to safely and rapidly remove the device in an emergency, what to do if the system stops responding, and how to respond if the system makes movements that are potentially unsafe to the patient. All such reasonably foreseeable situations must be anticipated, practiced and understood. Currently, the FDA has in place a mandate that companies provide at least some of this training. Thus, at a minimum, surgeons must be trained to meet these FDA standards.

The second aspect of training involves the use of the robot for specific operations. The simplest situation exists when a fully trained and competent laparoscopic surgeon begins to use a robotic system clinically. In this case, it is merely a matter of adding the specific knowledge of robotic technology to an existing set of clinical skills. A more complex situation is presented by the surgeon who elects to begin his or her minimally invasive endeavors using the robot. In this situation, the amount of learning required may be substantially greater. Full credentialing guidelines that address these situations are presented in Appendix I.

SAGES and MIRA recognize that surgical simulators may play an increasingly large role in surgical training in the future. However, at present there are no simulators that provide training equivalent to that obtained in a formal clinical setting. Thus, at present, simulators must remain an adjunct in the training of robotic surgeons.

II. Clinical Applications

The goal of the Clinical Applications subgroup was to focus on the status of robotic surgery applications as of June, 2006. Although robotic surgery has shown great promise across a broad range of surgical disciplines, no level I data exist at this time to strongly support robotic surgery; conversely, no studies or anecdotal reports exist to suggest any increase in complication rates compared to conventional open or laparoscopic surgery.

In general, the literature regarding robotic surgery lags behind the clinical experience by several years. Current literature suggests that the primary clinical advantages of currently available robotic systems, compared to conventional open or laparoscopic surgery, include:

- Superior visualization including 3-dimensional imaging of the operative field
- Stabilization of instruments within the surgical field
- Mechanical advantages over traditional laparoscopy
- Improved ergonomics for the operating surgeon

Across multiple surgical specialties, robotic surgery was felt to offer the greatest advantage in complex reconstructive processes.

Limitations of current robotic technology include,among other technical constraints, lack of

haptics (force feedback), size of the devices, instrumentation limitations (both size and variety), lack of flexibility of certain energy devices, and problems with multi-quadrant surgery (current devices are deployed typically for single quadrant application).

Overall, the technically exceptional laparoscopic surgeon may derive little benefit from robotic surgery. However, surgical robots may serve as an "enabling technology" for many surgeons, allowing them to provide complex minimally invasive procedures to a broad range of patients. The potential advantages of robotic surgery extend across many different surgical subspecialties.

Pediatric Surgery: Over 50 different types of abdominal and thoracic procedures have been performed in pediatric patients. Neonates and infants have also undergone robotic procedures safely and with excellent results. In particular, robotic surgery may present advantages for the Kasai procedure, choledochal cyst repair, and thoracic tumor excision. It may also be beneficial in abdominal and thoracic procedures requiring reconstruction. The major limitation is the size of the robotic instruments in relation to the pediatric patient.

Gynecology: Robotic surgery has shown promise in hysterectomy for both benign and malignant disease, as well as myomectomy. In myomectomy, the robot may provide substantial benefit by allowing minimally invasive fertility sparing options. It is also beneficial for tubal reconstruction. The robot may provide potential advantages for pelvic reconstructive surgery.

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General Surgery: With present technology, robotic surgery is best suited to procedures limited to one quadrant of the abdomen that present challenging access: specifically those requiring fine dissection, micro-suturing or reconstruction. Reports have been published with use for cholecystectomy, but with no findings of improved outcomes nor safety. Reports for solid organ surgery, as adrenalectomy, have not found particular advantage, noted increased cost, but did prove feasibility. Procedures where it may be of particular value include Heller myotomy, paraesophageal hernia repair, gastric bypass, gastric resection for neoplasm, biliary reconstructive surgery, transhiatal esophagectomy, transthoracic esophageal surgery, distal pancreatectomy with splenic preservation, and selected colorectal procedures. It may hold promise for pancreatic head resection and hepatectomy, but experience to date is limited. In resections for neoplasm, robotic surgery may help to enhance the completeness of lymph node dissection.

Although there is a substantial cost disadvantage to using the robot for simple procedures such as cholecystectomy and fundoplication, these procedure may present an excellent opportunity for surgeons early in their robotic learning curve to acquire increasingly more advanced skills.

Urology: Robotic surgery has been shown to offer substantial advantages over conventional minimally invasive surgery in several urological procedures. While the most mature outcomes data in the field of robotics are for radical prostatectomy, robotics may also offer advantages for cystectomy, pyeloplasty, nephrectomy (partial, complete and donor) and ureteral reimplantation. Resection of bladder neoplasm may also be approached robotically with a lower incidence of postoperative ileus. Robotic surgery may ultimately replace open surgery for some complex urological procedures.

SAGES
Society of American Gastrointestinal and Endoscopic Surgeons
http://www.sages.org

Thoracic Surgery: Robotic surgery offers clear benefits in the resection of solid thoracic tumors, particularly those located in the apex of the chest. Esophageal tumors such as leiomyomas may also be resected robotically.

Otorhinolaryngology/Head and Neck Surgery: Transoral robotic surgery is presently under study. Preliminary data indicate utility for transoral resections of benign and malignant lesions of the pharynx and larynx. Oncologic resections of the supraglottis, tonsil and tongue base have been shown to be feasible with potential advantages compared to traditional approaches. Preliminary evidence indicates that these advantages may include avoidance of mandibulotomy, avoidance of tracheostomy, decreased operative time, reduced requirements for complex reconstructions, and avoidance of external excisions.

Limitations of the present technology preclude transnasal and otologic procedures because of instrument size and functionality. Current otorhinolaryngology procedures are performed under IRB approval as FDA approval is still pending. Further use of robotic surgery in the head and neck will await the development of smaller instruments and more flexible robotic tools.

Limitations across specialties: Overall, the Clinical Applications subgroup felt that the 3 major impediments to the clinical use of robots are cost, training issues and lack of outcomes data. Among the previously mentioned technical limitations, the primary technical limitation of robotic surgery is the difficulty in performing procedures that extend over a large area, such as multiquadrant abdominal surgery. These limitations will likely ease as robotic devices evolve.

The use of surgical registries will be important in future studies of robotic surgery, particularly those evaluating short- and long-term surgical outcomes.

III. Cost/Benefit Analysis of Robotic Surgery

The cost/benefit analysis of robotic surgery involves a complex combination of numerous variables. Costs of the surgical robot include capital acquisition, limited use instruments, team training expenses, equipment maintenance, equipment repair, and operating room setup time. At present it is unknown whether robotic surgery will affect complication rate, length of stay, or length of patients' convalescence. Any analysis of robotic surgery must ensure that an appropriate comparison to alternative therapies is being made. In some cases robotic surgery should be compared to open surgery while in others to laparoscopic or alternative minimally invasive techniques.

Capital Acquisition Cost

The treatment of the capital acquisition cost will vary across institutions. In some cases the cost analysis will not include the capital purchase cost, while in others the allocation of this investment and depreciation will be assessed on a per case basis. Donations, institutional technology investment decisions, or marketing programs may or may not enter the cost analysis. Multidisciplinary team training is an up front investment that can be capitalized and requires inclusion in the initial analysis.

Instrumentation

The number of different robotic instruments utilized varies from case to case. Current instruments are limited to a fixed number of uses, unrelated to instrument wear. Since repeated reuse of instruments lowers the per case cost, an important future goal should be indefinitely reusable instruments.

Equipment Maintenance and Repair

The cost of maintaining, servicing, and repairing these highly complex devices represents a significant portion of the yearly cost. We estimate that the sum of these costs each year is approximately 10% of the capital acquisition cost. Reducing this expense should be an important goal of future device development.

Operating Room Time

The cost analysis of operating room time includes multiple variables: room setup time, time for draping and docking the robot, skin to skin procedure time, undocking/storage time, and room turnover time. These factors are improved by effective team training, attention to efficient procedures, surgeon and team experience, and initial patient selection. Small increases in overall operating room time become significant only when additional personnel are required, overtime is paid, or fewer cases per shift can be accomplished.

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Complication Rates

Complications have been shown to have a significant impact on the cost of care. It is generally felt that the use of robotics shortens the learning curve for acquiring complex minimally surgical skills. At present, there are no studies suggesting that robotic procedures performed by experienced robotic surgeons have different complication rates either better or worse than other comparable techniques.

Length of Stay

Comparison of robotic surgery to alternative techniques requires procedure by procedure analysis since there will be instances where robotic surgery is appropriately compared to minimally invasive techniques and others where it is compared to open techniques. Also, it should be remembered that length of stay affects cost centers outside the operating room. Decreased length of stay will counterbalance some of the increased operating room expenses associated with all forms of MIS. Length of stay may be affected by postoperative pain, intraoperative blood loss and complication rates. The differences between robotic and conventional surgery in these categories has not yet been adequately studied.

General Benefits

The desirable characteristics of current therapeutic robotic systems include platform stability, motion scaling, tremor reduction, excellent visualization, and articulating end effectors. Taken in

combination these characteristics create a highly effective therapeutic system for performing surgical procedures. Robotics have made minimally invasive techniques accessible to patients in whom the procedures could not be performed using conventional laparoscopic techniques. Furthermore, enhancements in precision may aid in the conduct of a variety of advanced MIS procedures.

Ergonomics

Both open and laparoscopic surgical procedures may be physically strenuous and have been associated with surgeon morbidity from repetitive use injury. Since the robotic surgeon sits comfortably in an ergonomically-designed workstation, the conduct of robotically-controlled procedures is generally more ergonomic for the operating surgeon. However, this benefit may not apply to the patient-side assistant. Such ergonomic differences will be magnified for lengthier procedures.

Learning Curve

Technically complex surgical tasks such as suturing present a substantial learning curve. These may be facilitated by the additional degrees of freedom inherent in articulated-arm robotic operating systems. Thus, articulated arm robots will potentially reduce technical skill acquisition time. They may enable surgeons to access difficult anatomic regions more easily, potentially speeding the introduction and clinical adoption of new MIS techniques.

Patient Return to Usual Activity

Some robotic surgical procedures may have better patient outcomes than their open or standard minimally invasive counterparts. Return to work benefits will vary based on the type of procedure and the population served

Risks of Robotic Surgery

Current surgical robots are continuously controlled by the surgeon and do not move autonomously. They possess neither artificial intelligence nor independent functioning. The robot remains a high-level, sophisticated tool used by the surgeon in the conduct of an operative procedure. Risks of robotic surgery can be categorized into those pertaining directly to the use of the robotic system and the general risks of the operative procedure.

Theoretically, the lack of haptic feedback in current robotic systems could lead to an increased risk of inadvertent tissue injury. However, to date, robotically performed operations have not been associated with higher clinical complication rates than their standard laparoscopic or open counterparts in experienced hands. In certain instances evidence exists that robotically performed procedures may be associated with a lower complication rate.

Robotic telesurgery, in which the surgeon may be located at some distance from the patient, poses unique risks. For example, precise control of the robot will be dependent upon the quality of the data connection between the surgeon's console and the operating room robot. Issues

pertaining to the quality and maintenance of such data connections may be beyond the control of the surgical team, but still represent a risk management challenge.

Mechanical Risks

All mechanical and electronic devices are subject to failure. Surgical robots – complex systems relying on a delicate interplay of hardware and software – are no exception. Current systems are designed with features intended to minimize the potentially deleterious effect of such failures on patients. Such features include system redundancy, so called "graceful" performance degradation or failure, fault tolerance, just-in-time maintenance, and system alerting. These are standards to which all high level systems should be held.

Institutional Risks

Healthcare institutions that employ high level technology as surgical robots in clinical practice need to develop and follow credentialing guidelines. The initiation of a robotic surgical program is similar to the introduction of any other novel, high-level, direct patient care technology, and should require appropriate training and credentialing (see Appendix I and II). In addition, each institution needs to develop a consistent policy concerning the nature of the procedures to be performed with regard to the need for IRB oversight. Such policy must take into account the nature of the proposed procedure itself. The institution also has an obligation to maintain the system consistent with manufacturer's guidelines.

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IV. Research

Surgical robots are now in their infancy. At present, there is only 1 commercially available general surgery robot in the United States. The robot does not perform any independent actions, but rather serves as a direct extension of the surgeon's own hand. In this sense, current robots are more correctly described as electromechanical surgical actuators. These devices faithfully reproduce a surgeon's action, as a 'mimic', but with no artificial intelligence nor automated subroutines. Since the term "robot" has come into general use in both the lay press and professional literature, and it is certainly a less cumbersome descriptor, we have used it throughout this document.

The present paradigm for surgical robotics is a limited one. A surgeon sits at a console, and his or her physical motions are translated via an elaborate electromechanical linkup to surgical instruments in the operative field. This paradigm does provide certain advantages in manipulating tissue, such as motion scaling and elimination of hand tremor. Current technology also has disadvantages, such as loss of haptic feedback. There is a significant amount of research and development that is evolving to bring us smaller, cheaper, faster, and safer devices with improved feature sets, such as haptic feedback. It is critical that future research in surgical robotics should not be tethered to the surgeon-at-a-console paradigm. Rather, research and development endeavors should address broader goals of a "grand vision" of computer/robotic assisted surgery. Some of these goals are enumerated below.

Instrumentation

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Current robotic instruments have evolved to provide a miniaturized 'endowrist' with degrees of freedom rivaling human capability. Future instrumentation will evolve in size and variety to further expand surgical capability.

'Smart instruments' are evolving so that dissection instruments can be imbued with capability to provide the user not only with mechanical dissection and retraction capabilities, but with 'smart sensing' capabilities, to provide the surgeon with information about tissue oxygenation, blood flow, molecular information, even tumor margin information.

Visualization

Computer enhanced vision has already restored 3-dimensional vision. Additional visual enhancement systems can further enhance the operator's vision, importing anatomic overlays, even 'help' heads-up displays. Visual system enhancements can also offer an array of 'optical biopsy' capabilities, as confocal microscopy, optical coherent tomography (OCT), and others, which can further enhance computer assisted visualization, enabling real-time microscopy, even molecular imaging.

Integrated Surgery

Robotic surgery presents an excellent opportunity to integrate anatomic and physiologic data into the operative field. Preoperative or even intraoperative imaging (e.g., CT, MRI, or ultrasound imaging) can reveal the three-dimensional topology of the operative field even before tissue is disturbed. Since the spatial coordinates (x, y, z axis) of the surgical instruments are "known" at all times by the surgical robot, the robotic interface provides an excellent platform through which this information can be integrated, registered, with the surgical device, so that the imaging information can be fused with the computer visual field, providing the potential for visual overlays of anatomy, function, even tumor mapping, such that the surgeon could 'see into' the tissues. Virtual barriers could be mapped into the operative field, identifying danger, or 'no fly zones', with the computer helping guide the surgeon away from potential hazard. This information could be used to guide surgical procedures intraoperatively, or even to simulate a proposed procedure before it is carried out. One of the more exciting potential areas of computer assisted interventional research relates to integrating imaging with interventional platforms.

Simulation

Robot workstations can serve as both consoles controlling robotic systems, but can also have potential to serve as simulator environments, with the capability to import patient specific information and allow rehearsal of patient specific procedures toward reduction in complications rates, learning curves, even development of new technical approaches.

In addition to providing input integration of imaging registered with an interventional robotic platform, robots can capture data regarding how a surgeon performs specific tasks. These 'black box' data could be used for quality control, teaching purposes, or even to "train" the computer to perform similar tasks independently.

Miniaturization

Future electromechanical technology may allow robots to be miniaturized to the point where they can enter the human body and perform surgery by remote control, or even autonomously. Such robots would potentially permit novel access paths to internal organs and could substantially decrease the invasiveness of surgical procedures. If such miniaturization is extended down to the level of "micro-machines", then surgery could theoretically be performed at the cellular level. Such extreme miniaturization, while beyond current realization, would require extensive reworking of current surgical paradigms. However, the potential for new minimally invasive approaches is great.

In the near term, robotic platforms and instrumentation may evolve to enable single access port (SAP) surgery, with a device, that once deployed, provides, through a single port, a multi-capable platform providing vision and multiple effectors devices.

Improved Mobility

Current robots work best when the surgical field is limited to a relatively small area, such as a single quadrant of the abdomen. Future devices will need improved flexibility so that they can easily be deployed to access entire body cavities without reconfiguration. Mobility of the robotic device itself is also an issue – current devices are large and difficult to move, and do not lend themselves to use outside an operating room environment, such as in the battlefield. Mobility of robotic devices will improve as they miniaturization improves and the footprint of the devices becomes smaller.

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True Independent / Autonomous Robotic Surgery

Current devices do not exercise independent logic or reason and do not even serve to automate repetitive tasks in the way that a sewing machine does. A first step in this direction for future robots would be the automation of routine tasks such as sewing; i.e. the surgeon indicates a start point and a finish point and the robot completes the suture line. Robots could use "artificial intelligence" to learn from the surgeon operating the device. Thus, robots could move from telemanipulators to skilled assistants in the future. If a robot acquired technical or cognitive knowledge from a large group of surgeons, it could ultimately serve as a computerized "colleague" to provide technical assistance in routine or unusual operative situations.

Safety and Documentation of Outcomes

Ultimately, all research in surgical robots must be undertaken with the goal of improving patient care and safety. Patient safety and clinical outcomes must remain foremost in future research efforts.

To adequately assess the risks and benefits of robotic surgery now and in the future, and to assist in guiding future research efforts, it will be essential to have outcomes registries for robotic surgery. Only through such registries will it be possible to accurately compare robotic surgery to traditional approaches, to document quality of outcomes, and to help identify needed

no directions for development.

Surgical Team Robotic Augmentees

Just as current surgical robots can enhance human surgeon performance, devices already exist to enhance the surgical team. 'Penelope' is a commercially available robot to replace the scrub technicians. Next generation devices under development can enhance the work of scrub nurses, supply workers, among others. Future devices can further augment human capability, task performance, and enhance the surgical team.

Operating Room Integration

Just as an imaging system as a CT scanner is a computer with eyes, and a robot is a computer with arms, an operating room can become a computer system, with surgical robots integrated into perioperative workflow and process. Integrated computerized tracking of surgical activity, workflow, use of materials, devices, consumables, can enhance task performance, quality of care, and ultimately patient safety. Key will be standards development, 'plug and play' interoperability, modularity, and better understanding of human-system integration and limitations.

Enabling steps

To fully realize the future of computer assisted intervention/ robotics evolution, we will need transdisciplinary collaboration across not only surgical, interventional, and imaging disciplines, but with engineers and computer experts, backed with significant funding to realize the potential of the human-system interface. The prospects for enhancing patient care, quality, and safety are substantial. Further consensus efforts will be needed to define 'white papers' to serve as roadmaps for future research and development.

Appendix I: Guidelines for Institutions Granting Privileges in Therapeutic Robotic Procedures

Preamble

The International consensus group of 2006 of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) recommend the following guidelines for privileging qualified surgeons in the performance of surgical procedures utilizing therapeutic robotic surgical devices alone or in a hybrid fashion. The basic premise is that the surgeon(s) must have the judgment and training to safely complete the procedure as intended, as well as have the capability of immediately proceeding to an alternative therapy when circumstances so indicate.

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I. Principles of Privileging

A. Purpose

The purpose of this statement is to outline principles and provide practical suggestions to assist healthcare institutions when granting privileges to perform procedures utilizing these technologies. In conjunction with other organizations guidelines for granting hospital privileges, implementation of these methods should help hospital staffs ensure that surgery is performed in a manner assuring high quality patient care and proper procedure utilization.

B. Uniformity of Standards

Uniform standards should be developed which apply to all medical staff requesting privileges to perform procedures utilizing these technologies. Criteria must be established which are medically sound, but not unreasonably stringent, and which are universally applicable to all those wishing to obtain privileges. The goal must be the delivery of high quality patient care. Surgical proficiency should be assessed for every surgeon, and privileges should not be granted or denied solely based on the number of procedures performed. Ongoing review of results and comparison to published data and/or recognized benchmarks is encouraged.

C. Responsibility for Privileging

The privileging structure and process remain the responsibility of the institution at which privileges are being sought. It should be the responsibility of the specialty department, through its chief to recommend privileges for individual surgeons to perform procedures. These recommendations should then be approved by the appropriate institutional committee, board, or governing body.

D. Definitions

Must/Shall - Mandatory recommendation

Should - Highly desirable recommendation

May/Could - Optional recommendation; alternatives may be appropriate

Documented Training and Experience

1. Case list that must specify the applicant's role (primary surgeon, co-surgeon, first assistant, chief resident, junior resident or observer). Complications, outcomes, and conversion to traditional techniques should be included if known. The applicant must specify if these details are not known.
2. Summary letter from preceptor and/or program director and/or chief of service (should state if applicant can independently and competently perform the procedure in question).

Privileging - The process whereby a specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization based on evaluation of the individual's credentials and performance.

Competence or Competency - A determination of an individual's capability to perform up to defined expectations.

Credentials - Documented evidence of licensure, education, training, experience, or other qualifications.

Complete Procedural Conduct - Competency of the applicant and/or institution regarding patient selection, peri-procedural care, conduct of the operation, technical skill and equipment necessary to safely complete a procedure and the ability to proceed immediately with the traditional open procedure.

Formal Course - A formal course alone is not appropriate training to begin performing a procedure independently. The course should be taught by instructors with appropriate clinical experience, and have a curriculum that includes didactic instruction as well as hands on experience utilizing inanimate and/or animate models. The course director and/or instructor should provide a written assessment of the participant's mastery of course objectives. Documentation for certain courses consisting of only didactic instruction may consist of verification of attendance.

Therapeutic Robotic Procedures - The spectrum of procedures utilizing a human controlled computer assisted electromechanical system which converts information to targeted therapeutic action.

II. Minimum Requirements for Granting Privileges

Part II A is mandatory, and *must* be accompanied by either part II B, or II C and at least one component of II D.

A. Formal Specialty Training

Prerequisite training *must* include satisfactory completion of an accredited surgical residency program, with subsequent certification by the applicable specialty board or an equivalent as required by the institution.

B. Formal Training in Residency and/or Fellowship Programs

For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. This should also include the science and the techniques of access to the body cavity and area of surgery. This includes adequate clinical experience. The applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training and clinical experience.

C. No Formal Residency Training in Therapeutic Robotic Surgery

For those surgeons without residency and/or fellowship training which included structured experience in therapeutic robotic procedures, or without documented prior experience in these areas, a structured training curriculum is required. The curriculum should be defined by the institution, and should include a structured program. The curriculum should include didactic education on the specific technology and an educational program for the specialty specific approach to the organ systems. If the access is an intracavitary procedure then that experience and education should be a prerequisite to the training. Hands-on training, which includes experience with the device in a dry lab environment as well as a specialty-specific model which may include animate, cadaveric and /or virtual reality and simulation modeling, is necessary. Observation of live case(s) should be considered mandatory as well. Other teaching aids may include video review and interactive computer programs.

D. Practical Experience

1. Applicant's Experience – Documented experience that includes an appropriate volume of cases with satisfactory outcomes, equivalent to the procedure in question in terms of complexity. The chief of service should determine the appropriateness of this experience.

2. Initial clinical experience on the specific procedure must be undertaken under the review of an expert and may include assisting. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review.

3. Preceptor or proctor. - The specific role and qualifications of the expert must be determined by the institution. Criteria of *competency* for each procedure should be established in advance, and should include evaluation of: familiarity with instrumentation and equipment, *competence* in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure. The criteria should be established by the chief of service in conjunction with the specific specialty chief where appropriate. It is essential that mentoring be provided in an unbiased, confidential, and objective manner.

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E. Formal Assessment of Competency

When available, validated measures of competency should be used to further document the applicant's abilities. These may include knowledge, medical decision making, and/or technical skill assessments. This may include certificates of completion of training or validated assessment tools for competency or proficiency in a specific procedure, or set of similar procedures.

III. Institutional Support

It is necessary that the staff and technical support team undergo a similar formal technical

training with the device before its use in a clinical scenario. Therapeutic robotic surgery requires technical support and must be approached with a team concept.

IV. Maintenance of Privileges

A. Provisional Privileges

Once competence has been determined, a period of provisional privileges may be appropriate. The time frame and/or number of cases during this period should be determined by the chief of service and/or the appropriate institutional committee, board, or governing body.

B. Monitoring of Performance

Once privileges have been granted, performance should be monitored through existing quality assurance mechanisms at the institution. These mechanisms may be modified as appropriate, and should evaluate outcomes, as well as competency in the complete patient care process.

C. Continuing Medical Education

Continuing medical education related to the field should be required as part of the periodic renewal of privileges. Attendance at appropriate local, national or international meetings and courses is encouraged.

D. Renewal

An appropriate level of continuing clinical activity should be required. This should include review of quality assurance data, as well as appropriate CME activity, in addition to existing mechanisms at the institution designed for this purpose.

E. Denial of Privileges

Institutions denying, withdrawing, or restricting privileges should have an appropriate mechanism for appeal in place. The procedural details of this should be developed by the institution, and must satisfy the institution's bylaws and institutional recommendations.

Appendix II. Guidelines for Training in Therapeutic Robotic Procedures

Purpose:

To define guidelines for practical education in therapeutic robotics and its application to surgical specialties. A defined course should provide the necessary information, skill training and familiarization with the technology to initiate a mentored clinical experience. The completion of a course should be considered only as preparation for the performance of a mentored clinical experience as determined by individual institutions

Expert Instructor:

Must have substantial practical experience with the specific advanced technology and have utilized this technology in clinical applications with reported results and review. The individuals should have specialty specific experience and expertise in the advanced technology.

Didactics:

The length of this portion of the educational experience should reflect the complexity of the technology and the specialty specific procedure and the underlying experience of the students, as well as the incremental increase in the procedure and technology. This should allow a complete understanding of the technology, device function, altered functional status, basic troubleshooting, other technical issues, device parameters and limitations. Technology and team interactions should be addressed as well.

Procedure specific information should include indications, workup patient selection, instrumentation, preop preparation, patient and system positioning, port placement, procedural steps, complications and management. Learning curve related issues should be presented. Reported outcomes and expected perioperative course should be included.

Live Case Observation:

The observation of a complete procedure is an important part of a total preclinical training program. The experience should include procedure preparation, system set up, patient positioning, review of case selection and intraoperative technical aspects.

Hands on experience:

Hands on experience should include non clinical simulation encompassing system set up, connections, operation, and troubleshooting. Initial skill training should include basic and advanced techniques to develop adequate proficiency necessary to complete the intended procedure. Clinical simulation should include procedure specific modeling with successful completion of the key components utilizing an appropriate model for the expected procedures. It is recommended that advanced simulation tools be used when available. The complexity of the procedure may dictate the length of the time necessary to complete the tasks.

Residency programs:

It is recommended that specialty training programs include exposure to therapeutic robotic interventions as part of their curriculum. A structured curriculum on therapeutic robotic procedures should be included in programs providing clinical experience to their trainees.

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This Guideline was developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and Minimally Invasive Robotic Association (MIRA) Robotic Task Force. It was reviewed by the SAGES Guidelines Committee and approved by the SAGES Board of Governors November 2007.

NICE National Institute for Health and Care Excellence

NICE guidance

Laparoscopic repair of abdominal aortic aneurysm

Interventional procedure guidance
Published: 22 August 2007
nice.org.uk/guidance/ipg229

1 Guidance

1.1 There is adequate evidence of the safety and efficacy of laparoscopic repair of abdominal aortic aneurysm, but the technical demands are such that this procedure should not be used without special arrangements for consent and for audit or research.

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1.2 Clinicians wishing to undertake laparoscopic repair of abdominal aortic aneurysm should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the procedure and its place in the elective treatment of abdominal aortic aneurysm. They should provide patients with clear, written information. In addition, the patient should be informed of other available techniques, and told that conversion to open surgery may be necessary. Use of the Institute's information for patients ('Understanding NICE guidance') is recommended.

1.3 Clinicians undertaking this procedure should submit data on all patients to the National Vascular Database held by The Vascular Society.

1.4 Selection of patients should be performed by a multidisciplinary team experienced in the management of aortic aneurysms and able to offer alternative treatment options.

1.5 This procedure should be performed by vascular surgeons who have had training in advanced laparoscopic surgery, and are mentored in these techniques.

2 The procedure

2.1 Indications

2.1.1 Dilatation of the aorta forming an aneurysm occurs in about 2% of men over the age of 65 (it is less common in women). Small aneurysms may present no problems, but some continue to grow, and larger aneurysms can leak or rupture. This carries a high risk of mortality, even when it is possible to offer emergency surgery. Preventive treatment is often advised for patients with aneurysms that represent an appreciable rupture risk.

2.1.2 The traditional treatment for abdominal aortic aneurysm is open surgical repair. The aneurysm is opened and a graft is then sewn in above and below the weakened area to allow normal blood flow. A less invasive approach is now commonly used, involving endovascular stent graft placement via the femoral arteries, but not all aneurysms are suitable for endovascular treatment.

2.2 Outline of the procedure

2.2.1 Laparoscopic repair of abdominal aortic aneurysm can be done by hand-assisted laparoscopic surgery (HALS) or by the technically more demanding totally laparoscopic surgery (TLS). In HALS, a midline minilaparotomy incision is made for insertion of one of the surgeon's hands to aid the procedure. In both techniques, small skin incisions are made for insertion of a laparoscope and instruments to guide and/or perform the repair. Lumbar arteries and the inferior mesenteric artery are dissected and clipped. Clamps are applied above and below the aneurysm, the sac is opened and thrombus removed. A prosthetic vascular graft is anastomosed to the proximal and distal ends of the aorta. The aneurysm wall and the posterior parietal peritoneum may be closed to cover the graft.

2.3 *Efficacy*

2.3.1 In three non-randomised controlled trials, mean hospital length of stay (LOS) was 5.9 (HALS), 6.2 and 6.3 (TLS) days, compared with 9.4, 10.0 and 10.2 days following open repair. One non-randomised controlled study reported that mean LOS was broadly similar following HALS (7.4 days) and endovascular stenting (6.4 days).

2.3.2 In one case series, mean LOS was 5 days for TLS (n = 131) and 7 days for HALS (n = 215). In a second case series, mean LOS for HALS was reported as 4.4 days. There was a statistically significant difference in mean LOS between the first 30 patients (5.3 days) and the last 92 patients (4.1 days) treated at one institution (p = 0.001). For more details, refer to the 'Sources of evidence' section.

2.3.3 All Specialist Advisers considered this procedure to be novel and of uncertain efficacy. They considered key efficacy outcomes for this procedure to be successful complete repair, open conversion rates, operative time, intensive care unit and overall hospital LOS, patient quality of life, renal function and need for return to theatre. Some Specialist Advisers suggested that there would be longer operating times, particularly early in the learning curve.

2.4 *Safety*

2.4.1 Postoperative death rates following laparoscopic aneurysm repair have been reported as 3% (1/29) and 4% (1/24) (HALS), and 5% (3/60) and 10% (2/20) (TLS).

2.4.2 One non-randomised controlled trial reported that the rate of renal insufficiency was 2% (1/60) following laparoscopic repair compared with 11% (11/100) following open repair. Other complications reported following laparoscopic aneurysm repair include bleeding from the hypogastric artery in <1% (1/122; HALS) and bleeding requiring reoperation in 2% (1/60; TLS).

2.4.3 In three non-randomised controlled trials that compared laparoscopic aneurysm repair with open surgery, the mean operative time was longer in the laparoscopic (181 [HALS], 462 and 468 minutes [TLS]) than in the open surgery groups (136, 300 and 301 minutes, respectively; significance not reported). A fourth non-randomised controlled study comparing HALS with endovascular

stenting reported that mean operative time was longer in the HALS group (198 and 149 minutes, respectively; not statistically significant).

2.4.4 In one case series mean operative time was 257 minutes with HALS; in another it was 175 minutes with HALS and 265 minutes with TLS. For more details, refer to the 'Sources of evidence' section.

2.4.5 Safety outcomes highlighted by the Specialist Advisers were death within 30 days and late mortality, and major complications such as blood loss, infection, and multiple organ failure. They all agreed that the safety of this novel procedure is uncertain and that advanced training in laparoscopic surgical techniques is important.

2.5 *Other comments*

2.5.1 It was noted that the different laparoscopic techniques have differing technical demands and training requirements. The Committee considered that total cross-clamp time and long-term graft performance are important outcome measures.

3 Further information

3.1 The Institute has issued guidance on stent-graft placement in abdominal aortic aneurysm and endovascular stent-graft placement in thoracic aortic aneurysms and dissections.

Andrew Dillon
Chief Executive
August 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of laparoscopic repair of abdominal aortic aneurysm', January 2007.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

14 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have

regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

NICE National Institute for Health and Care Excellence

NICE guidance

Laparoscopic retroperitoneal lymph node dissection for testicular cancer

Interventional procedure guidance
Published: 22 March 2006
nice.org.uk/guidance/ipg158

1 Guidance

1.1 Current evidence on the efficacy of laparoscopic retroperitoneal lymph node dissection is limited and there are safety concerns about the procedure. It should therefore not be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake laparoscopic retroperitoneal lymph node dissection for testicular cancer should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the potential serious complications associated with this procedure and provide them with clear written information. In addition, use of the Institute's information for the public is recommended.
- Audit and review clinical outcomes of all patients having laparoscopic retroperitoneal lymph node dissection for testicular cancer.

1.3 This procedure is technically demanding and should only be performed in units with experience in open and laparoscopic techniques, and in the context of a multidisciplinary team.

1.4 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Patients with testicular cancer who have had the cancerous testicle removed may require resection of lymph nodes, depending on the type and extent of disease as defined by imaging and blood markers.

2.1.2 The standard method for retroperitoneal lymph node dissection is an open procedure through an additional incision. A modification to the standard approach is nerve-sparing retroperitoneal lymph node dissection, in which the lumbar postganglionic nerves are identified and preserved in order to preserve antegrade ejaculation. A laparoscopic approach has the theoretical advantages of reduced morbidity and shorter recovery time.

2.2 Outline of the procedure

2.2.1 The lymph nodes and lymph tissue that drains the testicle are removed laparoscopically, through small incisions in the abdomen. The number of nodes removed can vary from fewer than ten to over 50, and the limits of excision are defined by a predetermined template.

2.3 Efficacy

2.3.1 No local cancer recurrence was reported in a case series of 20 patients followed up for 10 months. In another case series, contralateral retroperitoneal recurrence was reported in 2% (1/65) of patients with stage I cancer at 45 months, but no relapse was recorded among 47 patients with stage II disease at 35 months. In another case series, 97% (179/185) of patients were relapse-free at 54–58 months' follow-up.

2.3.2 In a comparative trial, the mean postoperative hospital stay was 4 days for patients who had had the laparoscopic procedure. Patients who had had open surgery stayed in hospital for mean 10.6 days.

2.3.3 In an historically controlled study, the mean operative times for the first 14 patients undergoing laparoscopic retroperitoneal lymph node dissection were 9.3 hours for right-sided tumours and 5.8 hours for left-sided tumours. For the next 15 patients, the operating times were 5.9 and 4.0 hours, respectively, which were similar to the 4.3 and 4.1 hours taken for the open procedure (30 patients). In other case series, the mean operative times for the laparoscopic procedure were 3.7–6.0 hours; they varied according to operator experience and stage of the cancers.

2.3.4 The rate of conversion to open surgery in case series ranged from 3% (5/185) to 10% (2/20). For more details, refer to the Sources of evidence.

2.3.5 The Specialist Advisors noted that there is some controversy about whether the procedure should be used for diagnosis in early stage cancer.

2.4 Safety

2.4.1 In an historically controlled study, major bleeding occurred during the procedure in 3% (1/29) of patients, and during 13% (4/30) of open retroperitoneal lymph node dissections. In case series, intraoperative haemorrhage occurred in 5% (1/20) to 18% (9/49) of patients with stage I and stage II disease, respectively.

2.4.2 Retrograde ejaculation was reported in 0% (0/29 and 0/20) to 2% (3/185) of patients following laparoscopic retroperitoneal lymph node dissection. In the controlled study and case series, the incidence of lymphocoele was 4% (3/76) to 9% (16/185): in most cases this was minor and asymptomatic.

2.4.3 Other complications reported across the studies included: pressure sores in 14% (2/14) of patients; gonadal vessel injury in 10% (2/20); subcutaneous lymphoedema in 7% (1/15); chylous ascites in 5% (9/185) (no cases were reported following the introduction of a new dietary regimen); injury to the inferior mesenteric artery in 5% (1/20); renal artery or colon injury in 1% (2/185); and transient irritation of the genitofemoral nerve in 1% (1/76). For more details, refer to the Sources of evidence.

2.4.4 The Specialist Advisors noted that the theoretical adverse events included vascular injury, bowel perforation, incomplete resection, haemorrhage, and local

or port-site recurrence. They also noted that there may be increased risks when dissecting large nodal masses that encircle the aorta or vena cava.

Andrew Dillon
Chief Executive
March 2006

3 Further information

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of laparoscopic retroperitoneal lymph node dissection for testicular cancer', May 2005.

4 Changes since publication

The guidance was considered for reassessment in March 2009 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

20 January 2012: minor maintenance.

5 About this guidance

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

資料 18

シンガポール大学との高難度新規医療技術に関する意見交換について

日時　　：平成29年3月10日

場所　　：福島県立医科大学内

参加者　：　Prof Jimmy So(シンガポール大学　上部消化管外科　教授)
Prof Lee Chuen Neng(シンガポール大学　外科主任教授)

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奥村晃子(日本医療機能評価機構　EBM 医療情報部　課長)

意見交換概要:

○ シンガポールでは、高難度医療技術の導入にあたって、国が統一的なルールを課しているとうことはない。同様の制度で思いあたるとすれば、臓器移植などの医療行為については、国がこれらの医療行為ができる医療機関を認定する仕組みはある。

○ 他方、シンガポール大学附属病院は、臨床研究で行う場合の研究審査とは別に、病院独自のルールとして、高難度新規医療技術を医療として提供するにあたって、審査を行うことが義務づけられている。これは、シンガポール大学附属病院以外でも、大きな病院では概ね同様だと理解している。

○ シンガポール以外でも、高難度医療技術の導入にあたって、統一的なルールを課している国の話は聞いたことはない。 日本が、一部の機関が独自に取り組んでいる仕組みについて、医療安全の観点から、統一的な基準を法令で定めることは、画期的で非常にいい取組だと考える。